August 02, 2007 Response to May 03, 2007 Non-final Office Action

Ser. No. 10/519,376 Docket No. 100681-1P US (133087.06801)

REMARKS

- 1. Claims 1-10 were pending. Claims 1-10 have been amended, support for which can be found, for example, in the originally filed claims. Claim 7 (which is a "medical use claims" under common European Patent practice) has been re-written into a method of treatment claim (which is appropriate under the US Patent practice), support for which can be found, for example, at page 9, lines 16-28 and page 10, lines 1-7. Claim 9 has been amended to be an independent claim and to incorporate all the definitions in claim 8. New claim 11 has been added to reflect proper dependency. Other amendments reflecting proper grammar and punctuation are self-evident. No new matter has been introduced. Upon entry of the present amendments, claims 1-11 will be pending.
- 2. Claims 1-3, 5-7, and 10 stand rejected under 35 USC § 112, first paragraph, for allegedly lacking enablement for the term "prodrug." Applicant respectfully disagrees. Applicant respectfully direct the Examiner's attention to page 3, lines 28-32 and page 4, lines 1-15 of the specification, where the routine methodology (incorporated by references) to prepare prodrug (such as an *in vivo* cleavable ester) for compounds of formula I (having a carboxylic acid group on the benzene ring next to W) is disclosed. Solely to advance prosecution, Applicant has amended the term "prodrug" to the term "an *in vivo* cleavable ester", support for which can be found, for example, at page 3, lines 28-32 and page 4, lines 1-15 of the specification. In view of the current amendment, this rejection becomes moot. Moreover, one of ordinary skill in the art would appreciate that the carboxylic acid compound of the present invention can be readily converted to an *in vivo* cleavable ester, in view of the disclosure of the present specification coupled with the common knowledge of the art. Therefore, Applicant respectfully the rejection to claims 1-3, 5-7, and 10 under 35 USC § 112, first paragraph, to be withdrawn.
- 3. Claim 6 stands rejected under 35 USC § 112, first paragraph, for allegedly lacking enablement. More specifically, the Office asserts that the specification does not enable "preventing diabetes," and that the specification fails to enable treating and/or preventing insulin resistance. Applicant respectfully disagrees. At the outset, Applicant respectfully points out that insulin resistance is a different and independent condition from type 1 Insulin resistance is a "condition in which normal amounts of insulin are inadequate to produce a normal insulin response from fat, muscle and liver cells." See, the definition and information on the wikipedia website (available af

Ser. No. 10/519,376 Docket No. 100681-1P US (133087.06801)

http://en.wikipedia.org/wiki/Insulin resistance; for the convenience of the Office, a print out of the wikipedia definition of and information on insulin resistance is submitted together with this response). "High plasma levels of insulin and glucose due to insulin resistance often lead to metabolic syndrome and type 2 diabetes." See id.; see also page 1, lines 10-26. In contrast, type 1 diabetes is "an autoimmune disease that results in the permanent destruction of insulin producing beta cells of the pancreas." See the definition and information on the wikipedia website (available http://en.wikipedia.org/wiki/Diabetes mellitus type 1; for the convenience of the Examiner, a print out of the wikiepeida definition of and information on type 1 diabetes is submitted together with this response); see also, page 4 of the Office Action. Therefore, claim 6 is NOT directed to the treatment of type 1 diabetes (i.e, to treat conditions associated with lack of insulin or insulin deficiency). Instead, claim 6 is directed to insulin resistance, which is a common condition among type 2 diabetic patients (although some type 1 diabetic patients may or may not have insulin resistance condition, which is different from and independent of the insulin deficiency problem in the type 1 diabetic patients). Moreover, the compounds of the present invention are selective PPARa modulators, see, e.g., page 2, lines 10-11, and pages 49-50 of the specification; and there is an established nexus between PPAR modulations (such as PPARa agonist) and treatment of conditions associated with insulin resistance, see page 2, lines 3-8. Accordingly, Applicant respectfully submits that the present application is enabling for the method of treatment in claim 6 (as amended). Moreover, solely to advance prosecution, the term "preventing" has been deleted from claim 6. In view of the foregoing. Applicant respectfully requests the rejection to claim 6 under 35 USC § 112, first paragraph to be withdrawn.

- 4. Claims 7-8 stand rejected under 35 USC § 112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 4-a. More specifically, the Office asserts that the use claim 7 does not set forth any step. Applicant has re-written claim 7 (which is a "medical use claims" under common European Patent practice) into a method of treatment claim (which is appropriate under the US Patent practice), support for which can be found, for example, at page 9, lines 16-28 and page 10, lines 1-7 of the specification and the original claim as filed. In view of the current amendment, this rejection becomes moot.

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amendment, this rejection becomes moot.

4-b. More specifically, the Office asserts that the phrase of "R¹, R², R³, W and n are as previously defined" recited in claim 8 lacks sufficient antecedent basis and thus vague and indefinite. Applicant has amended claim 8 to be dependent from claim 1, support for which can be found in the specification as filed, for example, at page 6. Moreover, the definitions of R¹, R², R³, W and n are also recited in the amended claim 8. In view of the current

- 5. Claim 7 is rejected under 35 U.S.C. §101 as allegedly failing to set forth any steps involved in the process (resulting in an improper definition of a process). In view of the current amendment (which recites an administration step), this rejection also becomes moot.
- 6. Claim 10 stands rejected under 35 USC § 112, second paragraph, for allegedly being indefinite. More specifically, the Office assets that the phase "such as" renders the claim indefinite. Applicant has deleted the phase "such as hypertension" and added a new dependent claim 11 (dependent from claim 10) to reflect proper dependency under the current US patent practice. In view of the current amendment, this rejection becomes moot.
- 7. In view of the foregoing, Applicant respectfully requests reconsideration of the rejections in light of the above comments and amendments. Early allowance of all pending claims is respectfully requested. The Examiner is invited to contact Applicant's undersigned representative at (215) 981-4142 if there are any questions regarding Applicant's claimed invention.

The Commissioner is hereby authorized to debit any fee due or credit any overpayment to deposit account 50-0436.

Respectfully submitted,

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